



ADM
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

20PP

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

RECEIVED

MAR 12 2002

PUBLIC DOCKET

MEMORANDUM

February 28, 2002

SUBJECT: **Propanil** Revised Chronic Dietary Exposure Assessment (PC Code 028201); DP
Barcode D281060; Case 0226.

FROM: Sherrie L. Kinard, Chemist
Reregistration Branch II
Health Effects Division (7509C)

THROUGH: Alan Nielsen, Branch Senior Scientist
Reregistration Branch II
Health Effects Division (7509C)

and

D. Hrdy, Biologist
S. Piper, Chemist
Dietary Exposure Science Advisory Council (DE SAC)
Chemistry Science Advisory Council (ChemSAC)
Health Effects Division (7509C)

TO: Richard Griffin, Biologist
Reregistration Branch II
Health Effects Division (7509C)

Executive Summary

The Tier 3 chronic dietary exposure assessment was conducted for the selective postemergence herbicide propanil, determined as 3,4-dichloroaniline (3,4-DCA) and calculated as propanil, to determine the risks associated with uses of propanil for broadleaf and grass weed control on barley, oats, rice, and wheat commodities. Anticipated residues (ARs) from field trial data were utilized to estimate the dietary exposure to propanil in the diets of the U.S. population, as well as certain population subgroups. Refinements using percent crop treated (%CT) and processing information are incorporated into this assessment.

1/22

This assessment concludes that for all supported registered commodities, the estimated chronic dietary risks associated with the use of propanil do not exceed HED's level of concern (>100% PAD¹) for the general U.S. population and all population subgroups including the most highly exposed population subgroup, all infants <1 year of age. The chronic dietary risk for all infants <1 year of age is 13% of the chronic PAD.

Action Requested

Tier 3 chronic dietary exposure assessment was requested to determine the dietary risk estimates associated with the reregistration of propanil. The only registered uses of propanil in/on food/feed crops are barley, oats, rice, and wheat for the control of broadleaf and grass weeds. The Tier 3 chronic dietary exposure assessment for propanil is refined using average field trial residue data, %CT information, and processing factors where appropriate for barley, oats, rice, wheat, meat, milk, poultry and eggs.

This memo has been reviewed and approved by the Health Effects Division's Chemistry Science Advisory Council (9/5/01) and approved by Dietary Exposure Science Advisory Council reviewers (9/5/01).

Toxicological Information

In a meeting on 1/16/96, the HED Metabolism Assessment Review Committee (MARC) concluded that the residue to be regulated in plants and animals is propanil and residues convertible to 3,4-DCA; there is no need for individual quantitation of propanil metabolites (DP Barcode: D222631).

The MARC does not recommend aggregating residues of 3,4-DCA for the propanil and diuron risk assessments. 3,4-DCA is a significant residue of concern for propanil, but is not a residue of concern *per se* for diuron. The analytical method for quantifying residues of concern from diuron converts all residues to 3,4-DCA because 3,4-DCA can be easily detected and accurately measured, but 3,4-DCA was not a significant residue in any metabolism or hydrolysis study. Therefore, the MARC recommended that all residues convertible to 3,4-DCA would be included in the tolerance expression for diuron, because no validated enforcement method was available for quantification for the actual residues of concern for diuron. Additionally, propanil and 3,4-DCA was found to have caused methemoglobinemia, the endpoint of concern, but diuron has not shown to cause this effect.

¹ cPAD = chronic Population Adjusted Dose = $\frac{\text{Chronic RfD}}{\text{FQPA Safety Factor}}$

On July 19, 2001, the Hazard Identification Assessment Review Committee (HIARC) met to discuss acute and chronic hazard endpoint selection for dietary exposure to propanil. The chronic hazard endpoint selected for dietary exposure to propanil is listed below in Table 1.

In a meeting on September 10, 2001, the Food Quality Protection Act (FQPA) Safety Factor committee recommended that the 10X FQPA Safety Factor (as required by Food Quality Protection Act of August 3, 1996) be **retained at 10X** for the U.S. population and all population subgroups for assessing the potential dietary risks posed by propanil use (B. Tarplee memo, 09/19/01).

Chronic Endpoints:

Table 1: Doses and Endpoints Selected for Chronic Dietary Risk Assessment

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT
Acute Dietary		
Chronic Dietary	LOAEL = 9 UF = 300 FQPA = 10X	Increased methemoglobin and increased spleen weight in females, and small seminal vesicles and prostates in males.
		Chronic RfD = 0.03 mg/kg/day Chronic PAD = 0.003 mg/kg/day
Cancer	Suggestive evidence of carcinogenic potential by all routes of exposure, but not sufficient to assess human carcinogenic potential.	(1) Propanil induced testicular interstitial cell adenomas in male rats. The hepatocellular adenomas in female rats occurred only at an excessively toxic dose. The increase in commonly occurring malignant lymphomas in female mice added little to the overall weight of evidence for the carcinogenic potential of propanil. (2) Propanil was not mutagenic.

Cancer:

In accordance with the EPA Draft Guidelines for Carcinogen Risk Assessment (July, 1999), in a meeting on May 9, 2001 the CARC classified propanil into the category **“Suggestive evidence of carcinogenic potential by all routes of exposure, but not sufficient to assess human carcinogenic potential”**. The decision was based on the following weight-of-the-evidence considerations: (1) Propanil induced testicular interstitial cell adenomas in male rats. The hepatocellular adenomas in female rats occurred only at an excessively toxic dose. The increase in commonly occurring malignant lymphomas in female mice added little to the overall weight of evidence for the carcinogenic potential of propanil. (2) Propanil was not mutagenic (William F. Sette, 06/19/01).

Consumption Data and Dietary Risk Analysis

The propanil chronic dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model (DEEM™) software Version 7.73, which incorporates consumption data from USDA's Continuing Surveys of Food Intake by Individuals (CSFII), 1989-1992. The 1989-92 data are based on the reported consumption of more than 10,000 individuals over three consecutive days, and therefore represent more than 30,000 unique "person days" of data. Foods "as consumed" (e.g., apple pie) are linked to raw agricultural commodities and their food forms (e.g., apples-cooked/canned or wheat-flour) by recipe translation files internal to the DEEM software. Consumption data are averaged for the entire US population and within population subgroups for chronic exposure assessment.

For chronic exposure and risk assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange-juice) on the commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total estimated exposure. Exposure estimates are expressed in mg/kg body weight/day and as a percent of the cPAD. This procedure is performed for each population subgroup.

Residue Information

Propanil Use:

Propanil is a selective postemergence herbicide registered for use on barley, oats, rice, and wheat. Registered uses of propanil on barley, oats, and wheat are geographically limited to the states of MN, MT, ND, and SD whereas uses on rice are limited to the southern states. Propanil formulation classes registered for food/feed uses include the dry flowable, emulsifiable concentrate, soluble concentrate liquid, and flowable concentrate. These formulations are typically applied as broadcast treatments using ground or aerial equipment. Tolerances have been established and are listed in 40 CFR §180.274(a)(1) and (a)(2).

Chronic Assessment:

For chronic risk assessment, reported residues from submitted field trial studies were averaged and used in this assessment. FDA monitoring data are available; however, the data was determined to be inappropriate for use in this chronic dietary assessment. If a commodity had no reported detections in the field trial data, half the limit of detection (LOD) was used to account for possible exposure that could not be more precisely quantified. The weighted average estimate of %CT was incorporated into all chronic residue estimates.

Propanil residue estimates, or ARs (listed in Table 2) used in this chronic dietary exposure assessment, are based primarily on field trial data submitted by the registrant to support tolerances. The order of preference for the purpose of dietary exposure assessment is usually:

monitoring data > field trial data > tolerance; however, the available FDA monitoring data was determined to be inappropriate due to the lack of 3,4-DCA samples analyzed, and the multiresidue method used is listed as having variable recovery of 3,4-DCA. Therefore, averaged field trial residue data were used.

The Agency notes that field trial data are generally considered by HED as an upper-end or a worse case scenario of possible residues and are more suited to the requirements of tolerance setting, because it requires highest rates of application and shortest PHI, than to the requirements of dietary exposure assessment (when the most realistic estimate is desired).

Processing Factors and Percent Crop Treated:

Refinements using %CT information (D. Donaldson from the Biological and Economic Analysis Division, 02/21/01) and processing information (MRID: 00035687 and 00035688) have been incorporated into the dietary exposure analysis for chronic risk estimates. The requirement for a wheat processing study was waived based on the lack of residues in/on wheat grain (<0.01 ppm) resulting from a 5X exaggerated field trial study. The Agency does not expect residues to concentrate in the processed products of wheat; therefore, a 1X processing factor was used for all wheat commodities. In a submitted acceptable rice processing study, residues did not concentrate in polished rice and showed average concentration factors to be 3.5X for rice hulls and 4.6X for rice bran; therefore, a 1X processing factor was used for polished rice commodities and a processing factor of 4.6X was used for rice bran. Rice hulls were not used in the livestock diets since it is assumed that both bran and hulls would not be fed to the same animal. DEEM default processing factors were used unless otherwise noted in Table 2. The weighted average estimate of %CT was incorporated into all chronic residue estimates.

In percentage terms, of the total pounds applied, rice accounts for approximately 99% of propanil usage with 70% of the crop treated. Less than 1% of barley, oats, and wheat crops are treated with propanil (D. Donaldson from the Biological and Economic Analysis Division, 02/21/01).

Residue Estimates:

The qualitative nature of the residue in plants and animals is adequately understood based on acceptable metabolism studies conducted on rice and wheat, and on acceptable ruminant, poultry, and crayfish metabolism studies. The salient features of these plant metabolism studies along with the results of ruminant, poultry, and crayfish metabolism studies were presented to the HED Metabolism Committee on 1/16/96. The Committee was asked whether propanil residues convertible to should remain the residues of concern in plants and animals. The Metabolism Committee concluded that the residue to be regulated in plants and animals is propanil and residues convertible to 3,4-DCA; there is no need for individual quantitation of propanil metabolites.

Table 2: Anticipated Residue Values for Use in Calculating Chronic Exposure

Commodity	Data Used	Wtd. Ave. %CT	Processing Factors	Anticipated Residue (ppm)
Plant Commodities				
Barley	MRID 0007893	<1	1X	0.00025
Oats	MRID 0007893	<1	1X	0.00025
Oats-bran	MRID 0007893	<1	1X	0.00025
Rice-rough (brown)	MRIDs 42237101, 42237201, 43282801	70	1X	0.36
Rice-milled (white)	MRIDs 42237101, 42237201, 43282801	70	1X	0.36
Rice-wild	MRIDs 42237101, 42237201, 43282801	70	1X	0.36
Rice-bran	MRIDs 42237101, 42237201, 43282801	70	4.6X	0.36
Wheat-rough	MRIDs 00055546, 00111370	<1	1X	0.00035
Wheat-germ	MRIDs 00055546, 00111370, 43196002	<1	1X	0.00035
Wheat-bran	MRIDs 00055546, 00111370, 43196002	<1	1X	0.00035
Wheat-flour	MRIDs 00055546, 00111370, 43196002	<1	1X	0.00035
Wheat-germ oil	MRIDs 00055546, 00111370, 43196002	<1	1X	0.00035
Milk, Meat, Poultry and Eggs				
Milk-nonfat solids	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.0013
Milk-fat solids	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.0013
Milk sugar (lactose)	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.0013
Milk-based water	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.0013
Beef-meat byproducts	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.044
Beef-other organ meats	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.044
Beef-dried	Dairy Cattle Feeding Study MRID 44550101	NA	1.92X	0.003
Beef-fat w/o bones	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.081
Beef-kidney	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.044

6/22

Commodity	Data Used	Wtd. Ave. %CT	F Factors	Anticipated Residue (ppm)
Beef-liver	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.018
Beef-lean (fat/free) w/o bones	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.003
Goat-meat byproducts	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.044
Goat-other organ meats	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.044
Goat-fat w/o bones	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.081
Goat-kidney	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.044
Goat-liver	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.018
Goat-lean (fat/free) w/o bones	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.003
Horsemeat	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.003
Rabbit	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.003
Sheep-meat byproducts	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.044
Sheep-other organ meats	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.044
Sheep-fat w/o bones	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.081
Sheep-kidney	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.044
Sheep-liver	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.018
Sheep-lean (fat/free) w/o bones	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.003
Pork-meat byproducts	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.16
Pork-other organ meats	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.16
Pork-fat w/o bone	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.30

7/22

Commodity	Data Used	Wtd. Ave. %CT	Processing Factors	Anticipated Residue (ppm)
Pork-kidney	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.16
Pork-liver	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.065
Pork-lean (fat free) w/o bone	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.010
Fish-shellfish	Magnitude of Residue in Crayfish MRID 43748101	NA	1X	0.03
Turkey-byproducts	Poultry Feeding Study MRID 44748201	NA	1X	0.031
Turkey-giblets (liver)	Poultry Feeding Study MRID 44748201	NA	1X	0.031
Turkey-fat w/o bones	Poultry Feeding Study MRID 44748201	NA	1X	0.007
Turkey-lean/fat free w/o bones	Poultry Feeding Study MRID 44748201	NA	1X	0.010
Turkey-other organ meats	Poultry Feeding Study MRID 44748201	NA	1X	0.031
Poultry-other-lean (fat free) w/o bones	Poultry Feeding Study MRID 44748201	NA	1X	0.010
Poultry-other-giblets (liver)	Poultry Feeding Study MRID 44748201	NA	1X	0.031
Poultry-other-fat w/o bones	Poultry Feeding Study MRID 44748201	NA	1X	0.007
Eggs-whole	Poultry Feeding Study MRID 44748201	NA	1X	0.028
Eggs-white only	Poultry Feeding Study MRID 44748201	NA	1X	0.028
Eggs-yolk only	Poultry Feeding Study MRID 44748201	NA	1X	0.028
Chicken-byproducts	Poultry Feeding Study MRID 44748201	NA	1X	0.031
Chicken-giblets (liver)	Poultry Feeding Study MRID 44748201	NA	1X	0.031
Chicken-fat w/o bones	Poultry Feeding Study MRID 44748201	NA	1X	0.007
Chicken-lean/fat free w/o bones	Poultry Feeding Study MRID 44748201	NA	1X	0.010

Commodity	Data Used	Wtd. Ave. %CT	Processing Factors	Anticipated Residue (ppm)
Chicken-giblets (excl.) liver	Poultry Feeding Study MRID 44748201	NA	1X	0.031
Veal-fat w/o bones	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.081
Veal-lean (fat free) w/o bones	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.003
Veal-kidney	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.044
Veal-liver	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.018
Veal-other organ meats	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.044
Veal-dried	Dairy Cattle Feeding Study MRID 44550101	NA	1.92X	0.003
Veal-meat byproducts	Dairy Cattle Feeding Study MRID 44550101	NA	1X	0.044

Note: Residue Data File (RDF). All data inputs in accordance with SOP 99.6.

Residue Estimates for Crops:

Barley and Oats: Residue data (MRID 00078930) for barley and oat grains treated with an EC formulation at 1.12-1.5 lb ai/A (~1X the maximum single and seasonal application rates) were non-detectable (<0.05 ppm); therefore, half the LOD was used incorporating %CT and processing information where appropriate.

Rice: In one rice field trial study (MRIDs 42237101 and 42237201; DP Barcode D175886, 6/22/92, R. Perfetti), 4 lb/gal EC formulation was applied at 4.0-8.0 lb ai/A (0.5-1.0X the maximum registered seasonal rate). Propanil residues (determined as base-releasable 3,4-DCA) in/on treated rice grain samples ranged from 0.03 ppm to 8.7 ppm; however, in another study (MRID 43282801; DP Barcode D205676, 9/8/94, C. Swartz) propanil residues (determined as base-releasable 3,4-DCA) ranged from 0.04 ppm to 2.20 ppm in/on rice grain resulting from two postemergence applications at 4 lb ai/A/application or a single postemergence application at 6 lb ai/A. The average residue value calculated from these studies was used incorporating %CT and processing information where appropriate.

The Agency notes that the high level of residues seen in these studies are a result of an application up to 2X the average seasonal application rate reported by BEAD (D. Donaldson from the Biological and Economic Analysis Division, 02/21/01).

Wheat: In field trial studies on wheat (MRIDs 00055546 and 00111370), the wheat were treated once with a representative EC formulation at 1.5-2.63 lb ai/A (~1.0-1.75X the

9/82

maximum permissible label rate) using ground or unspecified equipment. Wheat grain samples were <0.05 ppm (non-detectable) from all tests except two Canadian tests in which residues were 0.06-0.07 ppm. Additional data (MRID 43196002; DP Barcode D203514, 9/22/94, C. Swartz) indicate that propanil residues (determined as base-releasable 3,4-DCA) were <0.01 ppm (non-detectable) in/on wheat grain samples harvested at maturity (87 days) following a single postemergence application of the DF formulation at either 1.1 or 5.5 lb ai/A (1X or 5X the maximum label rate). The average residue value from these studies was calculated and used incorporating %CT and processing information where appropriate.

Residue Estimates for Meat, Milk, Poultry, and Eggs:

The potential for secondary transfer of propanil residues to animal commodities exists because the herbicide is registered for use on barley, oats, rice, and wheat; these crops include commodities which may be used as animal feed items. The maximum theoretical dietary burdens of propanil to beef cattle, dairy cattle, and poultry are calculated in the table below.

Table 3: Dietary burdens of propanil to beef cattle, dairy cattle, poultry and swine.

Feed Commodity	%CT	% Dry Matter ^a	% Diet ^a	Ave. FT Residue (ppm) ^b	Dietary Contribution (ppm) ^c
Beef Cattle					
Rice, grain	70	88	40	0.51	0.16
Rice, straw	70	90	10	5.3	0.41
Rice, bran	70	90	15	2.3	0.27
Wheat, forage	<1	25	25	0.09	0.0009
Wheat, straw	<1	88	10	12.3	0.014
TOTAL BURDEN			100		0.85
Dairy Cattle					
Rice, grain	70	88	40	0.51	0.16
Rice, straw	70	90	10	5.3	0.41
Wheat, forage	<1	25	50	0.09	0.0018
TOTAL BURDEN			100		0.57
Poultry ^c					
Rice, grain	70	--	60	0.51	0.21
Rice, bran	70	--	25	2.3	1.8
TOTAL BURDEN			85		2.0
Swine					
Rice, grain	70	--	65	0.51	1.8
Rice, bran	70	--	15	2.3	1.3
TOTAL BURDEN			80		3.1

^a As per Table 1 (OPPTS Guideline 860.1000).

^b HAFT level based on data from field trials (MRID 42237101, 42237201, 43282801, 42237301, 43282801, 44768801, 00111370 and 00055546).

10/22

c Ruminant contribution = $[AFTR \div \%DM] \times \%diet$ and poultry contribution = $AFTR \times \%diet \times \%CT$.

d Rice hulls and bran are cattle feed items; however, it is assumed that both bran and hulls would not be fed to the same animal. In addition, rice hulls are high in silica and are used with caution in cattle feeding (from personal communication with J. Stokes, 5/15/01).

e Rice hulls (15% of poultry diet) and bran are poultry feed items; however, it is assumed that both bran and hulls would not be fed to the same birds simultaneously with rice grain (rough rice). Propanil is also registered on other small grains used in poultry diets (barley, oats, and wheat). As the percent of small grain crop treated with propanil <1% (per registrant), and the contribution of small grains to the DB is negligible compared to rice, these commodities were not included in calculating the DB for poultry.

Ruminant feeding study

An acceptable ruminant feeding study (MRID 44550101) is available. Four groups of Holstein dairy cows were dosed orally once daily following the morning milking for 28 days with either rice-based rations containing field-aged residues at 3.9 ppm (propanil equivalents) or gelatin capsules fortified with propanil at dose levels equivalent to 15, 45, and 150 ppm (mg/kg diet on a dry weight basis). The feeding levels depicted in the study are approximately equivalent to 4.6X (rice-fed), 17.6X, 52.9X, and 176.5X, respectively, the anticipated maximum dietary burden of 0.85 for beef cattle. The feeding levels for dairy cattle are approximately equivalent to 6.8X (rice-fed), 26.3X, 78.9X, and 263.2X with a dietary burden of 0.57 ppm. Milk samples were collected on Days 0, 1, 3, 7, 11, 14, 18, 21, 24, and 27. Dairy cows were sacrificed within 4-10 hours of the final dose administration. At sacrifice, samples of fat (composite omental and perirenal), muscle (round and loin), liver, and kidney (both) were collected. A GC/NPD method (slightly modified version of EN-CAS Method No. ENC-9/90) was used in the analyses of milk and cattle tissue samples.

Table 4: Residues determined as 3,4-DCA and calculated as propanil from the ruminant feeding study and the anticipated residues for beef commodities.

Matrix	Residues at 15 ppm Dose Level (ppm)	Anticipated Residue (ppm)
Muscle	<0.05	0.003
Liver	0.31	0.018
Kidney	0.77	0.044
Fat	1.42	0.081
Milk	0.035	0.0013

Based on the ruminant feeding study, the feeding levels for swine are approximately equivalent to 1.3X, 4.8X, 14.5X, and 48.4X with a dietary burden of 3.1 ppm.

11/22

Table 4: Residues determined as 3,4-DCA and calculated as propanil from the ruminant feeding study and the anticipated residues for swine commodities.

Matrix	Residues at 15 ppm Dose Level (ppm)	Anticipated Residue (ppm)
Muscle	<0.05	0.010
Liver	0.31	0.065
Kidney	0.77	0.16
Fat	1.42	0.30

Poultry feeding study

An acceptable poultry feeding study (MRID 44748201) is available. Laying hens were dosed orally for 28 consecutive days with either rice-based rations containing field-aged residues at 3.7 ppm (propanil equivalents) or gelatin capsules fortified with propanil at dose levels equivalent to 5, 15, or 50 ppm in the diet. The feeding levels depicted in the study are approximately equivalent to 1.8X (rice-fed), 2.5X, 7.5X, and 25.0X, the maximum theoretical dietary burden (MTDB) for poultry of 2.0 ppm. Eggs were collected twice a day (morning and evening) in the 24-hour period following dosing. Control and treated hens were sacrificed within 16-20 hours of the final dose administration, and samples of liver, composite muscle (thigh and breast), and fat were collected. Egg and tissue samples were analyzed for residues of propanil using a GC/NPD method (modified version of EN-CAS Method No. ENC-9/90).

Table 5: Residues determined as 3,4-DCA and calculated as propanil from the poultry feeding study and the anticipated residues for poultry commodities.

Matrix	Residues at 15 ppm Dose Level (ppm)	Anticipated Residue (ppm)
Muscle	0.076	0.010
Liver	0.236	0.031
Fat	<0.05	0.007
Eggs	0.212	0.028

Fish

The registrant has submitted adequate data (MRID 43748101) depicting magnitude of the residue in crayfish. Residues of propanil and its metabolites, determined as base-releasable DCA and expressed as propanil equivalents, were <0.01-0.03 ppm in/on the edible portion of crayfish harvested 7-8 months following two applications of the 4 lb/gal EC formulation at ~4 lb ai/A/application, for a total rate of ~8 lb ai/A (1x the maximum seasonal application rate) to drained rice paddy sites. Based on these data, a residue value of 0.03 ppm was used for shellfish.

12/22

Results and Discussion

Uncertainties:

Propanil residue estimates, or ARs (listed in Table 2) used in this chronic dietary exposure assessment are based primarily on field trial data, submitted by the registrant to support tolerances. Field trial residue data are generally considered by HED as an upper-end or a worse case scenario of possible residues and are more suited to the requirements of tolerance setting, because it requires highest rates of application and shortest PHI, than to the requirements of dietary exposure assessment (when the most realistic estimate is desired).

The agency notes that there is a degree of uncertainty in extrapolating exposures for certain population subgroups from the general U.S. population which may not be sufficiently represented in the consumption surveys, (e.g., nursing and non-nursing infants or Hispanic females). Therefore, dietary risks estimated for these population subgroups were included in representative populations having sufficient numbers of survey respondents (e.g., all infants or females, 13-50 years).

Chronic Exposure Analysis: (Tier 3)

A chronic dietary exposure analysis for propanil was performed utilizing the DEEM™ software. The input values include the anticipated residues incorporating %CT and processing factors for commodities on which propanil is used. The calculated chronic dietary exposure (residue x consumption) was compared to a cPAD of 0.003 mg/kg/day, which reflects a FQPA factor of 10X for the U.S. population and all population subgroups. The results of the chronic dietary analysis are attached (Attachment 2).

Table 6: Chronic Dietary Risk Estimates

Population	Exposure mg/kg/day	% Chronic PAD
U.S. Population	0.000165	6
All Infants (<1 year)	0.000379	13
Children 1-6 years	0.000351	12
Children 7-12 years	0.000235	8
Females 13-50 years	0.000129	4
Males 13-19 years	0.000148	5
Males 20+ years	0.000144	5
Seniors 55+ years	0.000105	4

Conclusions

The chronic dietary risk estimates associated with the use of propanil do not exceed HED's level of concern for any population subgroup. The chronic dietary exposure estimate for all infants <1 year of age (the highest exposed population subgroup) is 13% of the cPAD. A complete listing of the chronic dietary results is in attachment 2. The chronic significant contributor was identified as rice-milled (white).

Attachments

Attachment 1: Residue Information

Attachment 2: Results of Chronic Dietary Exposure Analysis

Attachment 3: Commodity Contribution Analysis

Attachment 4: BEAD Memo of Percent Crop Treated Estimates

cc: Sherrie L. Kinard (RRB2), Propanil Reg. Std. File, Propanil Subject File, RF, LAN. RD/I: Propanil Team Review (8/26/01), Chemistry SAC (9/5/01), Dietary Exposure SAC (9/4/01).

14/22

7509C: RRB2: S. Kinard: CM#2:Rm 722B: 703-305-0563: 2/28/02.

ATTACHMENT 1

U.S. Environmental Protection Agency

DEEM Chronic analysis for PROPANIL

Residue file: C:\MyFiles\Propanil\Dietary\PropanilChronic.RS7

Ver. 7.73

1989-92 data

Adjust. #2 NOT used

Analysis Date 09-20-2001

Residue file dated: 09-20-2001/14:05:30/8

Reference dose (RfD) = 0.003 mg/kg bw/day

Comment: Tier 3 using ARs for grains, meat, milk and poultry. FQPA included in RfD.

Food Crop			RESIDUE	Adj. Factors	
Code	Grp	Food Name	(ppm)	#1	#2
265	15	Barley	0.000250	1.000	1.000
269	15	Oats	0.000250	1.000	1.000
270	15	Rice-rough (brown)	0.360000	1.000	1.000
271	15	Rice-milled (white)	0.360000	1.000	1.000
276	15	Wheat-rough	0.000350	1.000	1.000
277	15	Wheat-germ	0.000350	1.000	1.000
278	15	Wheat-bran	0.000350	1.000	1.000
279	15	Wheat-flour	0.000350	1.000	1.000
318	D	Milk-nonfat solids	0.001300	1.000	1.000
319	D	Milk-fat solids	0.001300	1.000	1.000
320	D	Milk sugar (lactose)	0.001300	1.000	1.000
321	M	Beef-meat byproducts	0.044000	1.000	1.000
322	M	Beef-other organ meats	0.044000	1.000	1.000
323	M	Beef-dried	0.003000	1.920	1.000
324	M	Beef-fat w/o bones	0.081000	1.000	1.000
325	M	Beef-kidney	0.044000	1.000	1.000
326	M	Beef-liver	0.018000	1.000	1.000
327	M	Beef-lean (fat/free) w/o bones	0.003000	1.000	1.000
328	M	Goat-meat byproducts	0.044000	1.000	1.000
329	M	Goat-other organ meats	0.044000	1.000	1.000
330	M	Goat-fat w/o bone	0.081000	1.000	1.000
331	M	Goat-kidney	0.044000	1.000	1.000
332	M	Goat-liver	0.018000	1.000	1.000
333	M	Goat-lean (fat/free) w/o bone	0.003000	1.000	1.000
334	M	Horsemeat	0.003000	1.000	1.000
335	M	Rabbit	0.003000	1.000	1.000
336	M	Sheep-meat byproducts	0.044000	1.000	1.000
337	M	Sheep-other organ meats	0.044000	1.000	1.000
338	M	Sheep-fat w/o bone	0.081000	1.000	1.000
339	M	Sheep-kidney	0.044000	1.000	1.000
340	M	Sheep-liver	0.018000	1.000	1.000
341	M	Sheep-lean (fat free) w/o bone	0.003000	1.000	1.000
342	M	Pork-meat byproducts	0.160000	1.000	1.000
343	M	Pork-other organ meats	0.160000	1.000	1.000
344	M	Pork-fat w/o bone	0.300000	1.000	1.000
345	M	Pork-kidney	0.160000	1.000	1.000
346	M	Pork-liver	0.065000	1.000	1.000
347	M	Pork-lean (fat free) w/o bone	0.010000	1.000	1.000
349	F	Fish-shellfish	0.030000	1.000	1.000
355	P	Turkey-byproducts	0.031000	1.000	1.000
356	P	Turkey-giblets (liver)	0.031000	1.000	1.000
357	P	Turkey--fat w/o bones	0.007000	1.000	1.000
358	P	Turkey- lean/fat free w/o bones	0.010000	1.000	1.000

360 P	Poultry-other-lean (fat free) w/	0.010000	1.000	1.000
361 P	Poultry-other-giblets(liver)	0.031000	1.000	1.000
362 P	Poultry-other-fat w/o bones	0.007000	1.000	1.000
363 P	Eggs-whole	0.028000	1.000	1.000
364 P	Eggs-white only	0.028000	1.000	1.000
365 P	Eggs-yolk only	0.028000	1.000	1.000
366 P	Chicken-byproducts	0.031000	1.000	1.000
367 P	Chicken-giblets(liver)	0.031000	1.000	1.000
368 P	Chicken-fat w/o bones	0.007000	1.000	1.000
369 P	Chicken-lean/fat free w/o bones	0.010000	1.000	1.000
385 P	Chicken-giblets (excl. liver)	0.031000	1.000	1.000
398 D	Milk-based water	0.001300	1.000	1.000
399 15	Oats-bran	0.000250	1.000	1.000
408 15	Rice-bran	0.360000	4.600	1.000
409 15	Rice-wild	0.360000	1.000	1.000
424 M	Veal-fat w/o bones	0.081000	1.000	1.000
425 M	Veal-lean (fat free) w/o bones	0.003000	1.000	1.000
426 M	Veal-kidney	0.044000	1.000	1.000
427 M	Veal-liver	0.018000	1.000	1.000
428 M	Veal-other organ meats	0.044000	1.000	1.000
429 M	Veal-dried	0.003000	1.920	1.000
430 M	Veal-meat byproducts	0.044000	1.000	1.000
437 15	Wheat-germ oil	0.000350	1.000	1.000
449 P	Turkey-other organ meats	0.031000	1.000	1.000

ATTACHMENT 2

U.S. Environmental Protection Agency

Ver. 7.73

DEEM Chronic analysis for PROPANIL

(1989-92 data)

Residue file name: C:\MyFiles\Propanil\Dietary\PropanilChronic.RS7

Adjustment factor #2 NOT used.

Analysis Date 09-20-2001/14:06:25

Residue file dated: 09-20-2001/14:05:30/8

Reference dose (RfD, Chronic) = .003 mg/kg bw/day

COMMENT 1: Tier 3 using ARs for grains, meat, milk and poultry. FQPA included in RfD.

=====

Total exposure by population subgroup

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of Rfd
U.S. Population (total)	0.000165	5.5%
U.S. Population (spring season)	0.000168	5.6%
U.S. Population (summer season)	0.000170	5.7%
U.S. Population (autumn season)	0.000159	5.3%
U.S. Population (winter season)	0.000163	5.4%
Northeast region	0.000176	5.9%
Midwest region	0.000145	4.8%
Southern region	0.000179	6.0%
Western region	0.000155	5.2%
Hispanics	0.000259	8.6%
Non-hispanic whites	0.000143	4.8%
Non-hispanic blacks	0.000212	7.1%
Non-hisp/non-white/non-black	0.000306	10.2%
All infants (< 1 year)	0.000379	12.6%
Nursing infants	0.000084	2.8%
Non-nursing infants	0.000504	16.8%
Children 1-6 yrs	0.000351	11.7%
Children 7-12 yrs	0.000235	7.8%
Females 13-19 (not preg or nursing)	0.000149	5.0%
Females 20+ (not preg or nursing)	0.000115	3.8%
Females 13-50 yrs	0.000129	4.3%
Females 13+ (preg/not nursing)	0.000110	3.7%
Females 13+ (nursing)	0.000145	4.8%
Males 13-19 yrs	0.000148	4.9%
Males 20+ yrs	0.000144	4.8%
Seniors 55+	0.000105	3.5%
Pacific Region	0.000161	5.4%

ATTACHMENT 3

U.S. Environmental Protection Agency

DEEM Chronic analysis for PROPANIL

Residue file name: C:\MyFiles\Propanil\Dietary\PropanilChronic.RS7

Ver. 7.73

(1989-92 data)

Adjustment factor #2, NOT used.

Analysis Date 09-20-2001/14:06:41

Residue file dated: 09-20-2001/14:05:30/8

Reference dose (RfD, Chronic) = .003 mg/kg bw/day

COMMENT 1: Tier 3 using ARs for grains, meat, milk and poultry. FQPA included in RfD.

Complete commodity contribution analysis for
U.S. Population (total)

Crop Group = (M) Meat

Food Name	Residue (ppm)	Adjustment Factors		Exposure Analysis	
				mg/kg body wt/day	Percent of RfD
Beef-meat byproducts	0.044000	1.000	1.000	0.0000004	0.0%
Beef-other organ meats	0.044000	1.000	1.000	0.0000002	0.0%
Beef-dried	0.003000	1.920	1.000	no exposure	
Beef-fat w/o bones	0.081000	1.000	1.000	0.0000144	0.5%
Beef-kidney	0.044000	1.000	1.000	0.0000000	0.0%
Beef-liver	0.018000	1.000	1.000	0.0000001	0.0%
Beef-lean (fat/free) w/o bones	0.003000	1.000	1.000	0.0000023	0.1%
Goat-meat byproducts	0.044000	1.000	1.000	no exposure	
Goat-other organ meats	0.044000	1.000	1.000	no exposure	
Goat-fat w/o bone	0.081000	1.000	1.000	no exposure	
Goat-kidney	0.044000	1.000	1.000	no exposure	
Goat-liver	0.018000	1.000	1.000	no exposure	
Goat-lean (fat/free) w/o bone	0.003000	1.000	1.000	0.0000000	0.0%
Horsemeat	0.003000	1.000	1.000	no exposure	
Rabbit	0.003000	1.000	1.000	0.0000000	0.0%
Sheep-meat byproducts	0.044000	1.000	1.000	no exposure	
Sheep-other organ meats	0.044000	1.000	1.000	no exposure	
Sheep-fat w/o bone	0.081000	1.000	1.000	0.0000001	0.0%
Sheep-kidney	0.044000	1.000	1.000	no exposure	
Sheep-liver	0.018000	1.000	1.000	no exposure	
Sheep-lean (fat free) w/o bone	0.003000	1.000	1.000	0.0000000	0.0%
Pork-meat byproducts	0.160000	1.000	1.000	0.0000004	0.0%
Pork-other organ meats	0.160000	1.000	1.000	0.0000000	0.0%
Pork-fat w/o bone	0.300000	1.000	1.000	0.0000322	1.1%
Pork-kidney	0.160000	1.000	1.000	no exposure	
Pork-liver	0.065000	1.000	1.000	0.0000001	0.0%
Pork-lean (fat free) w/o bone	0.010000	1.000	1.000	0.0000033	0.1%
Veal-fat w/o bones	0.081000	1.000	1.000	0.0000001	0.0%
Veal-lean (fat free) w/o bones	0.003000	1.000	1.000	0.0000000	0.0%
Veal-kidney	0.044000	1.000	1.000	no exposure	
Veal-liver	0.018000	1.000	1.000	no exposure	
Veal-other organ meats	0.044000	1.000	1.000	no exposure	
Veal-dried	0.003000	1.920	1.000	no exposure	
Veal-meat byproducts	0.044000	1.000	1.000	no exposure	
Crop group subtotal				0.0000536	1.8%

Crop Group = (P) Poultry

Food Name	Residue (ppm)	Adjustment Factors		Exposure Analysis	
				mg/kg body wt/day	Percent of RfD
Turkey-byproducts	0.031000	1.000	1.000	0.0000001	0.0%
Turkey-giblets (liver)	0.031000	1.000	1.000	0.0000000	0.0%
Turkey--fat w/o bones	0.007000	1.000	1.000	0.0000001	0.0%
Turkey- lean/fat free w/o bone	0.010000	1.000	1.000	0.0000010	0.0%
Poultry-other-lean (fat free)	0.010000	1.000	1.000	0.0000000	0.0%
Poultry-other-giblets(liver)	0.031000	1.000	1.000	no exposure	
Poultry-other-fat w/o bones	0.007000	1.000	1.000	0.0000000	0.0%
Eggs-whole	0.028000	1.000	1.000	0.0000102	0.3%
Eggs-white only	0.028000	1.000	1.000	0.0000003	0.0%
Eggs-yolk only	0.028000	1.000	1.000	0.0000001	0.0%
Chicken-byproducts	0.031000	1.000	1.000	0.0000000	0.0%
Chicken-giblets(liver)	0.031000	1.000	1.000	0.0000001	0.0%
Chicken-fat w/o bones	0.007000	1.000	1.000	0.0000003	0.0%
Chicken-lean/fat free w/o bone	0.010000	1.000	1.000	0.0000043	0.1%
Chicken-giblets (excl. liver)	0.031000	1.000	1.000	0.0000000	0.0%
Turkey-other organ meats	0.031000	1.000	1.000	0.0000000	0.0%
Crop group subtotal				0.0000166	0.6%

Crop Group = (F) Fish

Food Name	Residue (ppm)	Adjustment Factors		Exposure Analysis	
				mg/kg body wt/day	Percent of RfD
Fish-shellfish	0.030000	1.000	1.000	0.0000013	0.0%
Crop group subtotal				0.0000013	0.0%

Crop Group = (D) Dairy Products

Food Name	Residue (ppm)	Adjustment Factors		Exposure Analysis	
				mg/kg body wt/day	Percent of RfD
Milk-nonfat solids	0.001300	1.000	1.000	0.0000005	0.0%
Milk-fat solids	0.001300	1.000	1.000	0.0000004	0.0%
Milk sugar (lactose)	0.001300	1.000	1.000	0.0000005	0.0%
Milk-based water	0.001300	1.000	1.000	0.0000078	0.3%
Crop group subtotal				0.0000093	0.3%

Crop Group = (15) Cereal Grains

Food Name	Residue (ppm)	Adjustment Factors		Exposure Analysis	
				mg/kg body wt/day	Percent of RfD
Barley	0.000250	1.000	1.000	0.0000000	0.0%

20/22

Oats	0.000250	1.000	1.000	0.0000000	0.0%
Rice-rough (brown)	0.360000	1.000	1.000	0.0000082	0.3%
Rice-milled (white)	0.360000	1.000	1.000	0.0000739	2.5%
Wheat-rough	0.000350	1.000	1.000	0.0000000	0.0%
Wheat-germ	0.000350	1.000	1.000	0.0000000	0.0%
Wheat-bran	0.000350	1.000	1.000	0.0000000	0.0%
Wheat-flour	0.000350	1.000	1.000	0.0000005	0.0%
Oats-bran	0.000250	1.000	1.000	0.0000000	0.0%
Rice-bran	0.360000	4.600	1.000	0.0000012	0.0%
Rice-wild	0.360000	1.000	1.000	0.0000003	0.0%
Wheat-germ oil	0.000350	1.000	1.000	0.0000000	0.0%

Crop group subtotal				0.0000843	2.8%
---------------------	--	--	--	-----------	------

Population subgroup total				0.0001651	5.5%
---------------------------	--	--	--	-----------	------

Environmental Protection Agency Ver. 7.73
 DEEM Chronic analysis for PROPANIL (1989-92 data)
 Residue file name: C:\MyFiles\Propanil\Dietary\PropanilChronic.RS7

Adjustment factor #2 NOT used.

Analysis Date 09-20-2001/14:06:41 Residue file dated: 09-20-2001/14:05:30/8

Reference dose (RfD, Chronic) = .003 mg/kg bw/day

COMMENT 1: Tier 3 using ARs for grains, meat, milk and poultry. FQPA included in RfD.

=====
 Critical Commodity Contribution Analysis for
 U.S. Population (total)

Total Exposure = .0001651 mg/kg bw/day

Crop groups with total exposure contribution > 10%

Foods/Foodforms with exposure contribution > 10%

Crop group	-----Exposure Analysis-----		
Food	mg/kg	% of Total	Percent
Foodform	body wt/day	Exposure	of RfD
Crop Group = (M) Meat			
Pork-fat w/o bone	0.0000322	19.51%	1.07%
Total for crop group	0.0000536	32.45%	1.79%
Crop Group = (P) Poultry			
Total for crop group	0.0000166	10.05%	0.55%
Crop Group = (15) Cereal Grains			
Rice-milled (white)	0.0000739	44.79%	2.46%
Total for crop group	0.0000843	51.04%	2.81%
Total for crop groups listed above:	0.0001544	93.54%	5.1%

U.S. Environmental Protection Agency

DEEM Chronic analysis for PROPANIL

Residue file name: C:\MyFiles\Propanil\Dietary\PropanilChronic.RS7

Ver. 7.73

(1989-92 data)

Adjustment factor #2 NOT used.

Analysis Date 09-20-2001/14:06:41 Residue file dated: 09-20-2001/14:05:30/8

Reference dose (RfD, Chronic) = .003 mg/kg bw/day

COMMENT 1: Tier 3 using ARs for grains, meat, milk and poultry. FQPA included in RfD.

Complete commodity contribution analysis for
All infants (< 1 year)

Crop Group = (M) Meat

Food Name	Residue (ppm)	Adjustment Factors		Exposure Analysis	
				mg/kg body wt/day	Percent of RfD
Beef-meat byproducts	0.044000	1.000	1.000	0.0000000	0.0%
Beef-other organ meats	0.044000	1.000	1.000	0.0000000	0.0%
Beef-dried	0.003000	1.920	1.000	no exposure	
Beef-fat w/o bones	0.081000	1.000	1.000	0.0000062	0.2%
Beef-kidney	0.044000	1.000	1.000	no exposure	
Beef-liver	0.018000	1.000	1.000	no exposure	
Beef-lean (fat/free) w/o bones	0.003000	1.000	1.000	0.0000010	0.0%
Goat-meat byproducts	0.044000	1.000	1.000	no exposure	
Goat-other organ meats	0.044000	1.000	1.000	no exposure	
Goat-fat w/o bone	0.081000	1.000	1.000	no exposure	
Goat-kidney	0.044000	1.000	1.000	no exposure	
Goat-liver	0.018000	1.000	1.000	no exposure	
Goat-lean (fat/free) w/o bone	0.003000	1.000	1.000	no exposure	
Horsemeat	0.003000	1.000	1.000	no exposure	
Rabbit	0.003000	1.000	1.000	no exposure	
Sheep-meat byproducts	0.044000	1.000	1.000	no exposure	
Sheep-other organ meats	0.044000	1.000	1.000	no exposure	
Sheep-fat w/o bone	0.081000	1.000	1.000	0.0000000	0.0%
Sheep-kidney	0.044000	1.000	1.000	no exposure	
Sheep-liver	0.018000	1.000	1.000	no exposure	
Sheep-lean (fat free) w/o bone	0.003000	1.000	1.000	0.0000000	0.0%
Pork-meat byproducts	0.160000	1.000	1.000	0.0000001	0.0%
Pork-other organ meats	0.160000	1.000	1.000	no exposure	
Pork-fat w/o bone	0.300000	1.000	1.000	0.0000093	0.3%
Pork-kidney	0.160000	1.000	1.000	no exposure	
Pork-liver	0.065000	1.000	1.000	no exposure	
Pork-lean (fat free) w/o bone	0.010000	1.000	1.000	0.0000009	0.0%
Veal-fat w/o bones	0.081000	1.000	1.000	0.0000000	0.0%
Veal-lean (fat free) w/o bones	0.003000	1.000	1.000	0.0000000	0.0%
Veal-kidney	0.044000	1.000	1.000	no exposure	
Veal-liver	0.018000	1.000	1.000	no exposure	
Veal-other organ meats	0.044000	1.000	1.000	no exposure	
Veal-dried	0.003000	1.920	1.000	no exposure	
Veal-meat byproducts	0.044000	1.000	1.000	no exposure	
Crop group subtotal				0.0000176	0.6%